

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

TWINSTRAND BIOSCIENCES, INC. &)	
UNIVERSITY OF WASHINGTON,)	
)	
Plaintiffs and)	
Counterclaim Defendants,)	
)	
v.)	Civil Action No. 21-1126-GBW-SRF
)	
GUARDANT HEALTH, INC.,)	
)	
Defendant and)	
Counterclaim Plaintiff.)	

REPORT AND RECOMMENDATION

Presently before the court in this patent infringement action are the following motions filed by plaintiffs Twinstrand Biosciences, Inc. (“Twinstrand”) and University of Washington (“UW;” together, “Plaintiffs”): (1) a partial motion to dismiss Counterclaims V to VIII for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6) and strike related affirmative defenses under Rule 12(f), (D.I. 38);¹ and (2) a motion to sever and stay Counterclaims I to IV, (D.I. 75).² Briefing on the motions is complete, and the court held oral argument on October 27, 2022. For the following reasons, I recommend that the court GRANT-IN-PART the motion to dismiss and strike, and DENY without prejudice the motion to sever and stay.

¹ The briefing associated with the pending motion to dismiss is found at D.I. 39, D.I. 43, and D.I. 48.

² The briefing and related filings associated with the pending motion to sever and stay are found at D.I. 76, D.I. 82, D.I. 83, and D.I. 86.

I. BACKGROUND

A. Plaintiffs' Infringement Claims

Plaintiffs filed this action on August 3, 2021, asserting infringement of U.S. Patent Nos. 10,287, 631 (“the ’631 patent”); 10,689,699 (“the ’699 patent”); 10,752,951 (“the ’951 patent”); and 10,760,127 (“the ’127 patent,” collectively, the “Asserted Patents”). (D.I. 1) The Asserted Patents claim duplex sequencing methods that allow reliable, early, non-invasive cancer detection and post-treatment cancer monitoring in patients by analyzing blood plasma. (*Id.* at ¶¶ 13, 22) Jesse Salk, M.D., Ph.D, and his co-inventors conceived of these inventions through their work at UW and subsequently founded TwinStrand, which exclusively licenses the Asserted Patents from UW to make the technology available to clinicians and researchers under the TwinStrand Duplex Sequencing™ technology platform. (*Id.* at ¶¶ 13-14, 25-26; D.I. 30 at ¶¶ 122-23) The Asserted Patents issued between May 2019 and September 2020. (D.I. 1 at ¶¶ 9-12)

The complaint alleges that defendant Guardant Health, Inc. (“Guardant”) sells sequencing method products and services that infringe the Asserted Patents, including the Guardant360 lab developed test, Guardant360 CDx, GuardantOMNI, Guardant Reveal, Guardant LUNAR-2, Guardant360 Response, and Guardant360 TissueNext (collectively, the “Guardant Kits” or “Accused Products”). (D.I. 1 at ¶¶ 27-28) Guardant’s customers use the Guardant Kits to collect tissue samples and return them to Guardant for sequencing using an allegedly infringing digital sequencing method. (*Id.* at ¶ 28)

B. Guardant’s Counterclaims

Guardant filed an answer to the complaint on October 1, 2021, (D.I. 10), and filed an amended answer and counterclaims on January 12, 2022, (D.I. 30). Counterclaims I to IV allege

that TwinStrand's Duplex Sequencing™ kits and methods infringe Guardant's U.S. Patent Nos. 10,801,063 ("the '063 patent"), 10,889,858 ("the '858 patent"), 11,118,221 ("the '221 patent"), and 11,149,306 ("the '306 patent; collectively, the "Counterclaim Patents"). (D.I. 30 at ¶¶ 134-39, 149-225) The Counterclaim Patents are directed to methods and systems for detecting genetic variants using liquid biopsy cancer assays, which are less painful, less expensive, quicker, and more comprehensive than traditional tumor-based genotyping assays. (*Id.* at ¶¶ 116-20, 130-33) The '063, '221, and '306 patents name Helmy Eltoukhy, AmirAli Talasaz, and Stefanie Ann Ward Mortimer as inventors, and the '858 patent names Mr. Talasaz and Ms. Mortimer as inventors. (D.I. 30, Exs. A-D) The Counterclaim Patents issued between October 2020 and October 2021. (*Id.* at ¶¶ 130-33) Guardant was assigned all rights, title, and interest to the Counterclaim Patents. (*Id.*, Exs. A-D)

Counterclaims V and VI seek declarations of unpatentability of Plaintiffs' '699 and '951 patents under 35 U.S.C. §§ 101, 115, and/or 135(b). (D.I. 30 at ¶¶ 226-43) According to Guardant, TwinStrand copied certain claims of the '699 and '951 patents from Guardant's U.S. Patent No. 9,834,822 ("the '822 patent") and Application No. WO2015/100427 ("the '427 application"), respectively. (*Id.* at ¶¶ 141, 145) As a result, Guardant alleges that Plaintiffs' '699 and '951 patents do not name the actual inventors of the claimed subject matter. (*Id.* at ¶¶ 228, 238)

Counterclaim VII alleges that the '699 patent is unenforceable due to TwinStrand's inequitable conduct during prosecution of the application leading to the patent's issuance. (*Id.* at ¶¶ 143, 147, 245-47, 271-73) On May 13, 2019, TwinStrand filed Application No. 16/411,066 ("the '066 application"), which later issued as the '699 patent. (*Id.* at ¶ 248) The '066 application names Jesse Salk, Lawrence Loeb, and Michael Schmitt as inventors and claims

priority to Provisional Application No. 61/613,413, which was filed on March 20, 2012. (*Id.*)

The counterclaims allege that claims 37-39 and 41-43 of the '066 application were exact copies of claims 1-3, 6-7, and 10 of Guardant's '822 patent, which issued on December 5, 2017. (*Id.* at ¶ 250) The named inventors of the '066 application cited Guardant's '822 patent in the Information Disclosure Statement ("IDS") they filed on June 18, 2019. (*Id.* at ¶ 252) However, they did not notify the United States Patent and Trademark Office ("USPTO") that certain claims of the '066 application were copied from the '822 patent. (*Id.* at 257)

Similarly, Counterclaim VIII alleges that the '951 patent is unenforceable due to TwinStrand's inequitable conduct during prosecution of Application No. 16/514,931 ("the '931 application"), which was filed on July 17, 2019, and led to the issuance of the '951 patent. (D.I. 30 at ¶ 274) The '931 application also names Jesse Salk, Lawrence Loeb, and Michael Schmitt as inventors and claims priority to Provisional Application No. 61/613,413, which was filed on March 20, 2012. (*Id.*) The counterclaims allege that claims 1 to 2 of the '931 application are near copies of claims 77 to 78 of Guardant's '427 application, which was published on July 7, 2015. (*Id.* at ¶ 275) The named inventors of the '931 application cited Guardant's '427 application in a different application, WO2017/100441, confirming their awareness of the reference two years before they filed the '931 application. (*Id.* at ¶ 277) Nonetheless, Counterclaim VIII alleges they did not notify the USPTO that claims 1 to 2 of the '931 application were effectively copied from the '427 application. (*Id.* at ¶ 282)

C. The Illumina Action

Two months after Guardant filed its answer and counterclaims, Illumina, Inc. ("Illumina") sued Guardant, Eltoukhy, and Talasaz in this court for correction of inventorship, trade secret misappropriation, and breach of contract (the "Illumina Action"). *Illumina, Inc. v.*

Guardant Health, Inc. et al., C.A. No. 22-334-GBW-CJB, D.I. 1 (D. Del. Mar. 17, 2022). The complaint states that Eltoukhy and Talasaz co-founded Guardant while they were still employed by Illumina. (D.I. 76, Ex. 1 at ¶¶ 2-3, 20-26) Eltoukhy and Talasaz allegedly misappropriated Illumina’s confidential information and trade secrets to develop Guardant’s technology and prepare the patent applications that subsequently issued as a number of patents, including the Counterclaim Patents. (*Id.* at ¶¶ 50, 54, 57, 62, 66, 91) Illumina seeks a declaratory judgment to name Illumina as at least a co-owner of the Counterclaim Patents based on Eltoukhy’s alleged assignments to Illumina. (*Id.* at ¶ 100)

A motion to dismiss Illumina’s complaint, which was filed on May 25, 2022, remains pending. (C.A. No. 22-334-GBW-CJB, D.I. 29) A motion to transfer filed on the same date was subsequently withdrawn. (*Id.*, D.I. 26; D.I. 69) On August 17, 2022, the court entered a scheduling order in the Illumina Action setting a fact discovery deadline of October 13, 2023, an expert discovery deadline of March 28, 2024, a dispositive motion deadline of April 10, 2024, and a trial date in September 2024. (*Id.*, D.I. 55)

D. The IPR Proceedings

Plaintiffs and Guardant have each filed five petitions for *inter partes* review (“IPR”) before the Patent Trial and Appeal Board (“PTAB”) challenging the Counterclaim Patents and the Asserted Patents, respectively. (D.I. 83 at ¶¶ 9-10) Institution decisions on Plaintiffs’ IPRs are expected between October 2022 and January 2023, and institution decisions on Guardant’s IPR petitions are anticipated between August and December 2022. (*Id.*)

E. The Foundation Medicine Actions

On November 9, 2017, Guardant sued its competitor, Foundation Medicine, Inc. (“FMI”), for infringement of four of Guardant’s patents (the “FMI I Action”). (C.A. No. 17-1616-LPS-

CJB, D.I. 1) In response, FMI asserted counterclaims against Guardant for inequitable conduct by Eltoukhy and Talasaz, who allegedly made material misrepresentations to the USPTO regarding the inventorship of certain Guardant patents by omitting Eltoukhy as an inventor because he was still subject to an assignment agreement with Illumina. (*Id.*, D.I. 168 at ¶¶ 57-75, 82-84, 91-93, 100-02, 109-11) Shortly before the case was to proceed to trial in November of 2020, a spoliation issue arose based on allegations that Eltoukhy deleted certain data. (*Id.*, D.I. 505) As a result of the spoliation issue, the court continued the trial indefinitely, and the parties subsequently reached a settlement agreement. (*Id.*, D.I. 513; D.I. 583)

Three years later, shortly after the spoliation allegations came to light in the FMI I Action, Guardant brought another suit against FMI for infringement of another set of related Guardant patents (the “FMI II Action”), including the ’063 patent at issue in Guardant’s counterclaims in the present action. (C.A. No. 20-1580-LPS, D.I. 1) FMI again brought inequitable conduct counterclaims for each of the patents-in-suit, alleging that Eltoukhy and Talasaz made material misrepresentations regarding the inventorship of the patents to the USPTO during prosecution. (*Id.*, D.I. 22 at ¶¶ 146-48, 155-57, 164-66, 173-75, 182-84, 191-93, 200-02)

II. DISCUSSION

A. Motion to Dismiss Counterclaims V to VIII

Rule 12(b)(6) permits a party to move to dismiss a complaint for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). When considering a Rule 12(b)(6) motion to dismiss, the court must accept as true all factual allegations in the complaint and view them in the light most favorable to the plaintiff. *Connelly v. Lane Constr. Corp.*, 809 F.3d 780, 790-91 (3d Cir. 2016). “Courts use the same standard in ruling on a motion to dismiss a

counterclaim under Rule 12(b)(6) as they do in assessing a claim in a complaint.” *Goddard Sys., Inc. v. Gondal*, C.A. No. 17-1003-CJB, 2018 WL 1513018, at *4 (D. Del. Mar. 27, 2018).

To state a claim upon which relief can be granted pursuant to Rule 12(b)(6), a complaint must contain a “short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(2). Although detailed factual allegations are not required, the complaint must set forth sufficient factual matter, accepted as true, to “state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009). A claim is facially plausible when the factual allegations allow the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Iqbal*, 556 U.S. at 663; *Twombly*, 550 U.S. at 555-56.

The court’s determination is not whether the non-moving party “will ultimately prevail,” but whether that party is “entitled to offer evidence to support the claims.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) (internal citations and quotation marks omitted). This “does not impose a probability requirement at the pleading stage,” but instead “simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of [the necessary element].” *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008) (quoting *Twombly*, 550 U.S. at 556). The court’s analysis is a context-specific task requiring the court “to draw on its judicial experience and common sense.” *Iqbal*, 556 U.S. at 663-64.

1. Inequitable conduct

An individual associated with the filing and prosecution of a patent application engages in inequitable conduct when he or she makes an affirmative misrepresentation of a material fact, fails to disclose material information, or submits false material information to the USPTO, with a

specific intent to deceive the USPTO. *See Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008). Allegations for each of these requirements must be pled with particularity pursuant to Federal Rule of Civil Procedure 9(b). *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328-29 (Fed. Cir. 2009).

[T]o plead the “circumstances” of inequitable conduct with the requisite “particularity” under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO. Moreover, although “knowledge” and “intent” may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.

Id. Although a party may plead facts upon “information and belief,” it must also set forth the “specific facts upon which the belief is reasonably based.” *Id.* at 1330.

a. Omissions

The parties do not meaningfully dispute that Guardant’s inequitable conduct counterclaims identify omissions with sufficient particularity. Specifically, Counts VII and VIII allege that named inventors Jesse Salk, Lawrence Loeb, Michael Schmitt, and patent attorney Lara J. Dueppen did not notify the USPTO that claims 37 to 39 and 41 to 43 of the ’066 application were copied from Guardant’s ’822 patent (D.I. 30 at ¶ 257), and claims 1-2 of the ’931 application were copied from Guardant’s ’427 application (*id.* at ¶ 282). These facts are pled with sufficient particularity to identify the alleged omissions.

b. Materiality

Guardant’s inequitable conduct counterclaims fail to satisfy the materiality requirement under either a per se or but-for standard. Counterclaims VII and VIII assert a per se materiality standard, alleging that the failure to notify the USPTO of copied patent claims amounts to

affirmative egregious misconduct. (D.I. 30 at ¶¶ 260-61, 285-86) In support of this contention, the counterclaims recite provisions pertaining to the inventors' duty to disclose under the Code of Federal Regulations and the Manual of Patent Examining Procedure ("MPEP"). (*Id.* at ¶¶ 254-59; 279-84) For instance, MPEP § 2001.06(d) requires an applicant to identify claims that are copied are substantially copied from a patent because the source of the copied claims is material information under 37 C.F.R. § 1.56. MPEP § 2001.06(d). Section 1.56 requires individuals associated with the filing and prosecution of a patent application to disclose to the USPTO "all information known to that individual to be material to patentability[.]" 37 C.F.R. § 1.56(a).

These allegations are insufficient to establish the per se materiality of the alleged omissions for purposes of the inequitable conduct standard. The Federal Circuit has expressly declined to adopt the definition of materiality set forth in 37 C.F.R. § 1.56 in analyzing claims for inequitable conduct. *See Therasense*, 649 F.3d at 1293-94 (rejecting definition of materiality in 37 C.F.R. § 1.56 for purposes of inequitable conduct because it sets a low bar for materiality and "would inevitably result in . . . patent litigators continuing to charge inequitable conduct in nearly every case as a litigation strategy."). Accordingly, a violation of the duty to disclose claim copying under MPEP § 2001.06(d) cannot form the basis for materiality on a cause of action for inequitable conduct. *See Flypsi, Inc. v. Dialpad, Inc.*, 2022 WL 3593132, at *5 (W.D. Tex. Aug. 22, 2022) (rejecting application of materiality test under MPEP § 2001.06(c) to the materiality inquiry on a claim for inequitable conduct).

Moreover, well-pleaded allegations of per se materiality must be based on affirmative acts of egregious misconduct, such as the submission of a false affidavit or declaration to the USPTO. *See Therasense*, 649 F.3d at 1292 (explaining that the per se materiality standard is an

exception applied only in cases of affirmative egregious misconduct); *Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, 1294 (Fed. Cir. 2012). Here, the parties do not dispute that the foundation of Guardant's inequitable conduct counterclaims is the alleged omission of claim copying information. Guardant cites no authority to suggest that per se materiality can be based on alleged omissions, as opposed to affirmative acts, in support of a claim for inequitable conduct. To the extent that Counterclaims VII and VIII are based on allegations of per se materiality, those claims cannot survive Plaintiffs' motion to dismiss.

Guardant's inequitable conduct counterclaims likewise fail to satisfy the but-for materiality standard. To assess the materiality of a withheld reference under the but-for standard, "the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference." *Therasense*, 649 F.3d at 1291. Plaintiffs argue that Counterclaims VII and VIII lack factual allegations leading to a plausible inference that an interference would have been triggered or the USPTO would have rejected the claims if they had notified the examiner of the claim copying. (D.I. 39 at 13-14) A review of the counterclaims supports Plaintiffs' position.

In the pleading, Guardant identifies the claims of the '699 and '951 patents that were allegedly copied from Guardant's '822 patent and '427 application, respectively, and states that the '699 and '951 patents would not have issued if Plaintiffs disclosed this alleged claim copying to the USPTO. (D.I. 30 at ¶¶ 257, 263, 282, 288) In support of this contention, Guardant explains that the named inventors and patent attorney Lara Dueppen disclosed claim copying in another instance, and no patent issued from U.S. Application No. 16/118,305 after the claim copying was disclosed. (*Id.* at ¶¶ 266-68, 291-93) The court takes judicial notice that this factual allegation was subsequently rendered false. *See Secured Mail Sols. LLC v. Universal*

Wilde, Inc., 873 F.3d 905, 913 (Fed. Cir. 2017) (“[A] court need not accept as true allegations that contradict matters properly subject to judicial notice or by exhibit, such as the claims and the patent specification.”) (internal quotation marks and citations omitted). On February 8, 2022, about a month after Guardant filed its inequitable conduct counterclaims, the claims of U.S. Application No. 16/118,305 issued without amendment as U.S. Patent No. 11,242,562. (D.I. 39, Ex. CC)

Counterclaims VII and VIII also state that identifying the copied claims of the ’699 and ’951 patents would have triggered an interference, leading to “a much more thorough and in-depth examination as to whether the claims” should be issued. (D.I. 30 at ¶¶ 262, 287) Plaintiffs challenge the likelihood that an interference would have been declared because the copied claims were later amended, and the ’699 and ’951 patents claim priority to a pre-AIA provisional application. (D.I. 39 at 14; D.I. 48 at 4-5) But the court need not delve into the significance of priority issues and claim amendments to determine that the interference allegations are insufficient to establish the materiality of the alleged claim copying. Counterclaims VII and VIII do not allege that Plaintiffs were likely to lose a potential interference, or that the claims of the ’699 and ’951 patents would not have issued as a result of an interference. On this record, Guardant has failed to plead that a potential interference would have adversely impacted the patentability of the ’699 and ’951 patent claims.

At oral argument on October 27, 2022, Guardant argued that Plaintiffs’ undisclosed claim copying was but-for material because it occurred more than one year after the ’822 patent had issued, thus, falling outside of the timeframe for triggering an interference proceeding. (10/27/2022 Tr.) Counterclaim VII alleges that Plaintiffs “deliberately and improperly copied claims from the ’822 Patent more than one year after issuance of the ’822 Patent in violation of

35 U.S.C. § 135(b),” and “[b]y doing so outside of the one-year timeframe, [Plaintiffs] attempted to evade an interference proceeding.” (D.I. 30 at ¶¶ 246, 272) But the pleading does not allege that the ’699 and ’951 patents would not have issued if the untimely claim copying had been disclosed or otherwise explain how the alleged violation of § 135(b) would have adversely impacted the issuance of the ’699 and ’951 patent claims.

Guardant’s reliance on *Diebold Nixdorf, Inc. v. Hyosung Tns, Inc.* does not change the court’s analysis. C.A. No. 19-1695-LPS, 2021 WL 861734, at *4 (D. Del. Mar. 4, 2021). In *Diebold*, the court found that the defendant adequately pleaded the but-for materiality of a prior art reference where “[t]he pleadings contain[ed] specific allegations” that the prior art reference “describes numerous reasons and motivations that would lead a person having ordinary skill in the art to the alleged inventions of the [asserted patent] with predictable results and expected success.” *Id.* Unlike in *Diebold*, the inequitable conduct allegations here are not based on an alleged failure to disclose a prior art reference. Guardant fails to explain how the alleged fact of undisclosed copying is analogous to an undisclosed prior art reference in a but-for materiality analysis. Unlike in *Diebold*, Guardant’s factual allegations in Counterclaims VII and VIII stop at the likelihood that an interference proceeding would have been triggered, without suggesting that the ultimate outcome of any interference proceeding would negatively affect the issuance of the ’699 and ’951 patents. Absent allegations regarding the outcome of the interference proceeding, Guardant cannot show that Plaintiffs’ claim copying would have adversely impacted the issuance of any claims in the ’699 and ’951 patents.

Because Guardant’s inequitable conduct counterclaims do not adequately establish the materiality of the alleged omissions, I recommend that the court grant Plaintiffs’ motion to dismiss Counterclaims VII and VIII.

c. Specific intent

Plaintiffs also challenge the sufficiency of Guardant’s deceptive intent allegations in Counterclaims VII and VIII. (D.I. 39 at 10-12) At the pleading stage, Guardant “need only allege facts from which the Court could reasonably infer that the patent applicant made a deliberate decision to deceive the PTO.” *Natera, Inc. v. Genosity Inc.*, C.A. No. 20-1352-LPS, 2022 WL 767602, at *5 (D. Del. Mar. 14, 2022) (quoting *Wyeth Holdings Corp. v. Sandoz, Inc.*, C.A. No. 09-955-LPS-CJB, 2012 WL 600715, at *7 (D. Del. Feb. 3, 2012)). But the facts alleged in Guardant’s counterclaims cannot sustain a reasonable inference that the named inventors and prosecution counsel made a deliberate decision to deceive the USPTO during the prosecution of the ’699 and ’951 patents by concealing their claim copying activities. *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1330-31 (Fed. Cir. 2009) (explaining that specific intent allegations must identify a specific individual who owed a duty of disclosure, knew of the specific material information, and made a deliberate decision to withhold it).

Guardant’s inequitable conduct counterclaims allege that the named inventors and prosecution counsel engaged in a “practice of copying claims into their own applications without disclosing that the claims are copied,” citing five instances of alleged claim copying.³ (D.I. 30 at ¶¶ 265, 290) This asserted pattern of conduct forms the basis for Guardant’s position that the inventors engaged in a purposeful effort to copy claims without disclosing to the USPTO that

³ Guardant also contends that the inventors’ disclosure of claim copying in connection with the ’305 application shows they “engaged in a systemic practice of copying claims” and had an incentive to withhold the information in subsequent prosecutions once the ’305 application did not issue as a patent. (D.I. 43 at 7) As explained at § II.A.1.b, *supra*, the ’305 application ultimately issued as U.S. Patent No. 11, 242,562. (D.I. 39, Ex. CC) Because Plaintiffs suffered no adverse consequences from their disclosure of claim copying during prosecution of the ’305 application, there is no reason to infer that the claim copying disclosure in that prosecution dissuaded the inventors from disclosing claim copying in connection with prosecution of the ’699 and ’951 patents.

those claims were copied. (D.I. 43 at 6-7) However, Guardant's own pleaded allegations undercut the inference it seeks to draw. In four of the five claim copying examples cited by Guardant, the pleading confirms that the allegedly copied references were disclosed to the examiner in an information disclosure statement ("IDS"). (D.I. 30 at ¶¶ 265, 290) Plaintiffs' pattern of disclosing the allegedly copied references in the IDS forecloses a reasonable inference that Plaintiffs sought to conceal the copying of those references. *See Allergan USA, Inc. v. Prolenium US Inc.*, C.A. No. 19-126-CFC-SRF, 2019 WL 7298569, at *8 (D. Del. Dec. 30, 2019) (concluding that the disclosure of a prior art reference in an IDS indicated a lack of specific intent to deceive the USPTO).

Guardant's allegations of the inventors' specific intent to conceal claim copying in the '699 patent are also implausible. Counterclaim VII states that Plaintiffs submitted exact copies of claims 1-3, 6-7, and 10 from Guardant's '822 patent in claims 37-39 and 41-43 of the '066 application, which led to the issuance of the '699 patent. (D.I. 30 at ¶ 250) In the briefing, Guardant concedes that the '699 patent claims are not exact copies of the '822 patent claims and offers to amend the pleaded allegation to correct the inaccuracy. (D.I. 43 at 8 n.1) Nonetheless, Guardant maintains that the claims are near-exact copies with immaterial differences, creating a strong inference that the claims were copied. (*Id.* at 8-10)

Accepting as true the substantial similarity of the copied claims in the '699 patent, Guardant's pleaded allegations still do not give rise to a reasonable inference that Plaintiffs intended to deceive the USPTO. Counterclaim VII expressly states that the '822 patent was disclosed in an IDS during prosecution of the '699 patent. (D.I. 30 at ¶ 252) The disclosure of the '822 patent in the IDS "points away from an intent to deceive," despite the fact that Plaintiffs did not specifically identify the allegedly copied claims for the examiner. *Pixion, Inc. v. Citrix*

Sys., Inc., 2012 WL 762005, at *6 (N.D. Cal. Mar. 8, 2012) (quoting *Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F.3d 1380, 1384 (Fed. Cir. 1998)).

Guardant's claim copying allegations in Counterclaim VIII also fail to give rise to a reasonable inference that the named inventors and prosecuting attorney specifically intended to conceal their claim copying during prosecution of the '951 patent. There is no averment that the prosecuting attorney had knowledge of the '427 application. The pleading alleges that the inventors were aware of Guardant's '427 application because they cited it in their own patent application filed two years before they submitted the application leading to the '951 patent. (D.I. 30 at ¶ 277) But "[a] reference may be many pages long, and its various teachings may be relevant to different applications for different reasons. Thus, one cannot assume that an individual, who generally knew that a reference existed, also knew of the specific material *information* contained in that reference." *Exergen*, 575 F.3d at 1330.

Such is the case here. Counterclaim VIII states that the inventors did not notify the USPTO that claims 1 and 2 of the '951 patent were copied from the '427 application, but it fails to suggest that the inventors were specifically aware of claims 77 and 78 from the '427 application or that they knew those claims were substantially similar to claims 1 and 2 of the '951 patent. (D.I. 30 at ¶¶ 275, 282) As a result, these allegations lack sufficient underlying facts to support a reasonable inference that the inventors of the '951 patent withheld claim copying information with a specific intent to deceive the USPTO. *See Exergen*, 575 F.3d at 1330 (explaining that, although knowledge and intent may be averred generally, an inequitable conduct claim must still set forth specific facts on which the averments are based).

Because Guardant has failed to adequately plead the materiality and intent prongs of their counterclaims for inequitable conduct, I recommend that the court dismiss Counterclaims VII and VIII of Guardant's pleading without prejudice.

2. Inventorship

Plaintiffs also seek dismissal of Guardant's Counterclaims V and VI, which aver that the '699 and '951 patents are unpatentable under 35 U.S.C. §§ 101, 115, and 135(b) for failure to name the actual inventors of the claimed subject matter. (D.I. 39 at 15-18) For the following reasons, I recommend that the court grant-in-part Plaintiffs' motion to dismiss Counterclaims V and VI. Specifically, I recommend that the court deny the motion to the extent that it seeks dismissal of Counterclaims V and VI under 35 U.S.C. §§ 101 and 115, and grant the motion to the extent that it seeks dismissal of Counterclaim V under 35 U.S.C. § 135(b).

a. Unpatentability under 35 U.S.C. §§ 101 and 115

The Federal Circuit has explained that "[a] patent is invalid if more or less than the true inventors are named," *Trovan, Ltd. v. Sokymat SA, Irori*, 299 F.3d 1292, 1301 (Fed. Cir. 2002), and "[c]onception is the touchstone of inventorship," *CODA Dev. S.R.O. v. Goodyear Tire & Rubber Co.*, 916 F.3d 1350, 1359 (Fed. Cir. 2019) (quoting *Acromed Corp. v. Sofamor Danek Grp., Inc.*, 253 F.3d 1371, 1379 (Fed. Cir. 2001)). The sufficiency of a cause of action for patent invalidity pursuant to 35 U.S.C. §§ 101 and 115 at the pleading stage is governed by Rule 8, as opposed to the heightened pleading standard of Rule 9(b). *See Belcher Pharms., LLC v. Hospira, Inc.*, C.A. No. 17-775-LPS, 2019 WL 2503159, at *1 (D. Del. June 5, 2019). Here, the parties dispute whether Counterclaims V and VI should be dismissed for failure to allege facts regarding the conception of the '699 and '951 patents. (D.I. 39 at 16-17; D.I. 43 at 12-13)

Counterclaims V and VI plausibly allege improper inventorship of the '699 and '951 patents. *See Belcher Pharms., LLC v. Hospira, Inc.*, C.A. No. 17-775-LPS, 2019 WL 2503159, at *1 n.1 (D. Del. June 5, 2019) (explaining that a patent may be invalid under 35 U.S.C. §§ 101 and 115 if it names the wrong inventors). The pleading avers that the inventions of the '699 and '951 patents were not made by the named inventors; instead, those claims were copied from Guardant's '822 patent and '427 application, respectively. (D.I. 30 at ¶¶ 141-42, 145-46, 233-34, 242) Guardant accuses TwinStrand of "shamelessly attack[ing] Guardant's patent portfolio by copying Guardant's own patent claims into TwinStrand patent applications—misrepresenting TwinStrand employees and founders as the true inventors of the claimed inventions[.]" (*Id.* at ¶ 124) While Plaintiffs accurately report that the pleading does not expressly refer to the "conception" of the '699 and '951 patents, the pleaded allegations give rise to a plausible inference that the named inventors of those patents did not conceive of the claimed inventions, which were instead copied from other references. (*Id.* at ¶¶ 124, 141, 145, 233-34, 242) Counterclaims V and VI also give rise to a plausible inference that the named inventors of Guardant's '822 patent and '427 application conceived of the claimed inventions in the '699 and '951 patents because those references are identified as the source of the copied claims. (*Id.* at ¶¶ 141-42, 145-46, 234, 242) Therefore, I recommend that the court deny Plaintiffs' motion to dismiss Counterclaims V and VI for unpatentability under 35 U.S.C. §§ 101 and 115.

Because portions of Counterclaims V and VI remain viable, I further recommend that the court deny Plaintiffs' request to dismiss UW as a counterclaim defendant. (D.I. 39 at 18)

b. Unpatentability under 35 U.S.C. § 135(b)

For purposes of the pending motion, the parties agree that the pre-America Invents Act ("AIA") version of 35 U.S.C. § 135(b) applies to the analysis of whether the '699 patent is

unpatentable as alleged in Counterclaim V. (D.I. 39 at 17-18; D.I. 43 at 14) Pre-AIA § 135(b) provides that “[a] claim which is the same as, or for the same or substantially the same subject matter as, a claim of an issued patent may not be made in any application unless such a claim is made prior to one year from the date on which the patent was granted.” 35 U.S.C. § 135(b). The parties dispute whether § 135(b) provides a cause of action for invalidity. (D.I. 39 at 18; D.I. 43 at 15-16)

Plaintiffs correctly argue that § 135(b) does not provide a cause of action for invalidity. (D.I. 39 at 18) The Federal Circuit has explained that “[b]oth the plain language of that provision and the relevant legislative history make clear that [§ 135] was intended to be a statute of repose, limiting the time during which an interference may be declared ‘so that the patentee might be more secure in his property right.’” *Berman v. Housey*, 291 F.3d 1345, 1351 (Fed. Cir. 2002) (quoting *Corbett v. Chisholm*, 568 F.2d 759, 765 (C.C.P.A. 1977)); *see also Regents of Univ. of Cal. v. Univ. of Iowa Research Found.*, 455 F.3d 1371, 1376 (Fed. Cir. 2006) (“[I]n order to serve as a statute of repose, section 135(b)(1) operates in conjunction with the PTO’s duty to declare interferences.”). Consequently, “a determination that the claims involved in an interference are not barred by § 135(b) is a condition precedent . . . that should be resolved before issues of priority and patentability are addressed.” *Id.* at 1352; *see Chiron Corp. v. Genentech, Inc.*, 268 F. Supp. 2d 1148, 1171 (E.D. Cal. 2002) (rejecting a claim that a patent was invalid under § 135(b) because the statute “is a procedural bar to interference proceedings, not a substantive basis upon which to declare the claims of a patent invalid.”).

Guardant cites the Federal Circuit’s decision in *Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577, 1584 (Fed. Cir. 1995), for the proposition that 35 U.S.C. § 282 should be read broadly to include invalidity defenses not expressly identified in the statute. According to Guardant, the

Federal Circuit's determination in *Quantum* that § 282 encompasses violations of 35 U.S.C. § 305 should be further extended to include violations of 35 U.S.C. § 135 in this case. (D.I. 43 at 15-16) Guardant's reasoning is inapplicable here because the cases are clear that § 135(b) is concerned with time limitations for declaring an interference and not a substantive basis for invalidity. See *Berman*, 291 F.3d at 1351; *Regents of Univ. of Cal.*, 455 F.3d at 1376; *Chiron Corp.*, 268 F. Supp. 2d at 1171. Therefore, I recommend that the court dismiss Counterclaim V for unpatentability of the '699 patent under 35 U.S.C. § 135(b).

B. Motion to Strike Guardant's Fourth, Eighth, and Twelfth Affirmative Defenses

Plaintiffs also ask the court to strike Guardant's Fourth, Eighth, and Twelfth Affirmative Defenses. Rule 12(f) permits a court to "strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). Motions under Rule 12(f) are generally disfavored. *Fesnak & Assocs., LLP v. U.S. Bank Nat'l Ass'n*, 722 F. Supp. 2d 496, 502 (D. Del. 2010). On a motion to strike, the court should construe all facts in favor of the nonmoving party and "should not grant a motion to strike a defense unless the insufficiency of the defense is clearly apparent." *Symbol Techs., Inc. v. Aruba Networks, Inc.*, 609 F. Supp. 2d 353, 356 (D. Del. 2009) (internal quotation marks and citation omitted). However, "a court is not required to accept affirmative defenses that are mere bare bones conclusory allegations, and may strike such inadequately pleaded defenses." *Sun Microsystems, Inc. v. Versata Enters., Inc.*, 630 F. Supp. 2d 395, 408 (D. Del. 2009). Rule 12(f) "has been used in this jurisdiction to strike affirmative defenses where a party has failed to state a corresponding claim upon which relief can be granted" under Rule 12(b)(6). *Wyeth Holdings*, 2012 WL 600715, at *4 (citing *Power Integrations, Inc. v. Fairchild Semiconductor Int'l Inc.*, C.A. No. 08-309-JJF-LPS, 2009 WL 4928024, at *8-10 (D. Del. Dec. 18, 2009)).

1. Fourth and Twelfth Affirmative Defenses

Guardant's Fourth and Twelfth Affirmative Defenses are coextensive with Counterclaims V and VI. For the reasons previously stated at § II.A.2.a, *supra*, I recommend that the court deny Plaintiffs' motion to strike Guardant's Fourth Affirmative Defense for failure to name the correct inventors and derivation. For the reasons previously stated at § II.A.2.b, *supra*, I recommend that the court grant Plaintiffs' motion to strike Guardant's Twelfth Affirmative Defense for failure to comply with the requirements of 35 U.S.C. § 135.

2. Eighth Affirmative Defense

In a footnote, Plaintiffs state that Guardant's Eighth Affirmative Defense for unclean hands "appears to cover (if not be co-extensive with) Guardant's inequitable-conduct counterclaims[.]" (D.I. 39 at 1 n.1) "[A]rguments raised in passing (such as, in a footnote), but not squarely argued, are considered waived." *John Wyeth & Brother Ltd. v. Cigna Int'l Corp.*, 119 F.3d 1070, 1076, n.6 (3d Cir. 1997). The defense of unclean hands is governed by a different standard than inequitable conduct. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011). Plaintiffs' arguments are directed to inequitable conduct. Therefore, I recommend that the court deny Plaintiffs' motion to strike Guardant's Eighth Affirmative Defense for unclean hands. *See Samsung Elecs. Co. v. Netlist, Inc.*, C.A. No. 21-1453-RGA, 2022 WL 3027312, at *5 (D. Del. Aug. 1, 2022) (finding argument to strike affirmative defense of unclean hands was waived where it was raised in a footnote and based on arguments pertaining to inequitable conduct).

C. Motion to Stay Counterclaims I to IV

Plaintiffs move this court to stay litigation on Counterclaims I to IV. (D.I. 76 at 1) A court has discretionary authority to grant a motion to stay. *See Landis v. N. Am. Co.*, 299 U.S.

248, 254-55 (1936); *Dentsply Int'l Inc. v. Kerr Mfg. Co.*, 734 F. Supp. 656, 658 (D. Del. 1990).

Courts consider three factors in deciding how to exercise this discretion: (1) whether a stay will simplify the issues for trial; (2) the status of the litigation, particularly whether discovery is complete and a trial date has been set; and (3) whether a stay would cause the non-movant to suffer undue prejudice from any delay or allow the movant to gain a clear tactical advantage.

See Am. Axle & Manuf., Inc. v. Neapco Holdings LLC, C.A. No. 15-1168-LPS, 2021 WL 616992, at *2 (D. Del. Feb. 17, 2021) (citing *Ethicon LLC v. Intuitive Surgical, Inc.*, C.A. No. 17-871-LPS, 2019 WL 1276029, at *1 (D. Del. Mar. 20, 2019)). On balance, these factors weigh against a stay in this case at this time.

1. Simplification of the issues for trial

Plaintiffs identify two ways in which a stay of litigation on Counterclaims I to IV is likely to simplify the issues for trial in this matter. First, Plaintiffs argue that ownership challenges to the Counterclaim Patents in the Illumina Action have the potential to impact Guardant's standing to assert the Counterclaim Patents in this action. (D.I. 76 at 8) Second, Plaintiffs suggest that a stay would allow the IPR proceedings on the Counterclaim Patents to proceed to institution decisions and possible invalidity determinations, which would narrow the asserted claims of those patents. (D.I. 76 at 11-12; D.I. 86 at 6)

Plaintiffs' first basis for simplification weighs somewhat in favor of granting a stay at this stage because a determination regarding the ownership of the Counterclaim Patents in the Illumina Action could be dispositive of Counterclaims I to IV in this action. But as Guardant explains, this result is not the only possible outcome. (D.I. 82 at 10-11) A motion to dismiss remains pending in the Illumina Action which could nullify Illumina's ownership challenges to Guardant's patents if it is granted. (C.A. No. 22-334-GBW-CJB, D.I. 29) At this juncture, it is

also speculative to assume that Illumina's claims will reach a judgment. For these reasons, the simplification factor does not weigh strongly in favor of staying the case.

Plaintiffs cite a number of cases for the proposition that a stay should be granted when challenges to patent ownership are pending in another case. (D.I. 76 at 9) But as Guardant explains, decisions on patent ownership were imminent in each of those cases, whereas the Illumina Action was filed well after this case and is not expected to go to trial until nearly a year after the scheduled trial in this case. (*See, e.g.*, D.I. 20; C.A. No. 22-334-GBW-CJB, D.I. 55); *see Optimal Golf Sols., Inc. v. Altex Corp.*, 2009 WL 10733424, at *1 (N.D. Tex. Sept. 30, 2009) (staying case where ownership of patent-in-suit was expected to be addressed by the bankruptcy court "in the coming weeks"); *Innovative Patented Tech., LLC v. Samsung Elecs. Co.*, 2008 WL 2726914, at *1 (S.D. Fla. July 10, 2008) (finding a stay appropriate where an earlier-filed case in another district makes a determination of patent ownership).

Plaintiffs' second basis for simplification does not weigh in favor of a stay at this stage because the PTAB has not yet decided whether to institute IPR proceedings on the Counterclaim Patents. *See Invensas Corp. v. Samsung Elecs. Co.*, C.A. No. 17-1363-MN-SRF, 2018 WL 4762957, at *3 (D. Del. Oct. 2, 2018) (concluding that the issue simplification factor weighs against a stay before the PTAB issues an institution decision).

2. Status of the litigation

The stage of the litigation is a neutral factor in this case. "Stays are favored when the 'most burdensome stages of the case—completing discovery, preparing expert reports, filing and responding to pretrial motions, preparing for trial, going through the trial process, and engaging in post-trial motions practice—all lie in the future.'" *Bio-Rad Lab'ys Inc. v. 10x Genomics, Inc.*, C.A. No. 18-1679-RGA, 2020 WL 2849989, at *1 (D. Del. June 2, 2020). Although expert

discovery and pretrial preparations still lie in the future, fact discovery is well underway, experts have been retained, and briefing on claim construction is complete. (D.I. 20 at ¶ 8(f)(i); 9/14/2022 Oral Order) Because the requested stay of this case is occasioned by the issues before the court in the Illumina Action, the comparatively early stage of that case also weighs against a stay. *See Dentsply Int'l, Inc. v. Kerr Mfg. Co.*, 734 F. Supp. 656, 658 (D. Del. 1990) (explaining that “[t]he disposition of the earlier case should not be delayed by the later filed litigation.” (quoting *La Chemise Lacoste v. Alligator Co., Inc.*, 60 F.R.D. 164, 176 (D. Del. 1973))).

3. Prejudice

The third and final factor weighs against a stay because courts generally recognize that staying proceedings between two direct competitors can result in prejudice to the nonmoving party, including the potential for lost market share and the erosion of goodwill. *See FMC Corp. v. Summit Agro USA, LLC*, C.A. No. 14-51-LPS-CJB, 2014 WL 3703629, at *5 (D. Del. July 21, 2014) (quoting *ImageVision.Net, Inc. v. Internet Payment Exch., Inc.*, C.A. No. 12-54-GMS-MPT, 2013 WL 663535, at *6 (D. Del. Feb. 25, 2013)); *SenoRx, Inc. v. Hologic, Inc.*, C.A. No. 12-173-LPS-CJB, 2013 WL 144255, at *9 (D. Del. Jan. 11, 2013). The fact that Plaintiffs and Guardant are not the only participants in the relevant market does not negate this prejudice. “[E]ven in cases where there [are] some number of other competitors in the market, so long as plaintiff and defendant [are] joint market participants and engaged in some level of competition, our Court has tended to find that some amount of potential prejudice is at play.” *FMC*, 2014 WL 3703629, at *6.

Guardant also persuasively argues that Plaintiffs will have a clear tactical advantage if their infringement claims on the Asserted Patents proceed to trial while Counterclaims I to IV remain paused. (D.I. 82 at 7) If the Illumina Action terminates in a manner favorable to

Guardant, or if the claims in the Illumina Action proceed past the pleading stage, a lengthy stay would prejudice Guardant due to the lost opportunity to enforce its patents and the delay in any potential recovery. *See Align Tech., Inc. v. 3Shape A/S*, C.A. no. 17-1646-LPS-CJB, 2018 WL 4292675, at *3 (D. Del. Sept. 7, 2018). Such prejudice outweighs the other factors for a stay.

On balance, the stay factors weigh against staying the proceedings with respect to Counterclaims I to IV. Therefore, I recommend that the court deny Plaintiffs' motion to stay, without prejudice to renew the request in the event that IPR proceedings are instituted or determinations of patent ownership are reached in the Illumina Action.

D. Motion to Sever Counterclaims I to IV

During the oral argument on October 27, 2022, counsel for Plaintiffs confirmed that the motion to sever rises and falls with the outcome of the motion to stay. (10/27/2022 Tr.) Having recommended that the court deny Plaintiffs' motion to stay for the reasons set forth at § II.C, *supra*, I further recommend denying Plaintiffs' motion to sever Counterclaims I to IV.

III. CONCLUSION

For the foregoing reasons, I recommend that the court GRANT-IN-PART Plaintiffs' Rule 12(b)(6) motion to dismiss Counterclaims V to VIII. (D.I. 38) Specifically, I recommend that the court DENY the motion to dismiss Counterclaims V and VI to the extent that those counterclaims are based on a failure to name the correct inventors under 35 U.S.C. §§ 101 and 115. I recommend that the court GRANT the motion to dismiss Counterclaim V to the extent that it is based on 35 U.S.C. § 135(b), and GRANT the motion to dismiss Counterclaims VII and VIII. I further recommend that the court GRANT Plaintiffs' motion to strike Guardant's Eighth and Twelfth Affirmative Defenses and DENY the motion to strike Guardant's Fourth

Affirmative Defense. Finally, I recommend that the court DENY Plaintiffs' motion to sever and stay Counterclaims I to IV without prejudice. (D.I. 75)

Given that the court has relied upon material that technically remains under seal, the court is releasing this Report and Recommendation under seal, pending review by the parties. In the unlikely event that the parties believe that certain material in this Report and Recommendation should be redacted, the parties shall jointly submit a proposed redacted version by no later than **November 4, 2022**, for review by the court, along with a motion supported by a declaration that includes a clear, factually detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *See In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019) (quoting *Miller v. Ind. Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994) (internal quotation marks omitted)). If the parties do not file a proposed redacted version and corresponding motion, or if the court determines the motion lacks a meritorious basis, the documents will be unsealed within thirty (30) days of the date the Report and Recommendation issued.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The objections and responses to the objections are limited to ten (10) pages each. The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the District Court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated March 7, 2022, a copy of which is available on the court's website, <http://www.ded.uscourts.gov>.

Dated: October 28, 2022



Sherry R. Fallon
UNITED STATES MAGISTRATE JUDGE